HYGIA
HEALTH SERVICES

K012956
Page 1 of 4

APR 11 2002

510(k) Summary

Summary

Substantial Equivalence Summary for the Hygia Health Services Reprocessed NuTech® Combo

In accordance with 21 CFR Part 807.92, this summary is submitted by:

Hygia Health Services, Inc.
2800 Milan Court
Suite 259
Birmingham, Alabama 35211

Date: August 28, 2001

1. Contact Person

Geoff M. Fatzinger
Director, Compliance and Regulatory Affairs
(205) 943-6670

2. Name of Device

Classification Name: Compressible Limb Sleeve
Common or Usual Name: Intermittent Pneumatic Compressible Limb Sleeve
Review Panel: Cardiovascular
Classification: Class II
Proprietary Name: Hygia Health Services Reprocessed NuTech® Combo.

3. Predicate Device

Classification Name:	Compressible Limb Sleeve
Common Name:	Intermittent Pneumatic Compressible Limb Sleeve
Classification:	Class II
Proprietary Name:	NuTech® Combination Foot and Calf Wrap

4. Statement of Substantial Equivalence

The Hygia Health Services Reprocessed NuTech® Combo employs no new technology other than the method used to reprocess the garments in order to allow the device to be utilized more than once. The Hygia Health Services Reprocessed NuTech® Combo is substantially equivalent to the NuTech® Combination Foot and Calf Wrap in that the basis of operation for both devices is the intermittent inflation of a single inflation chamber on two different devices simultaneously, one device placed around the patient's gastrocnemius muscle and the other placed around the plantar arch. The garments are then connected to a controller via a single inflation tube and snap-lock connector. Inflation of the garments is accomplished using ambient air, and a controller cycle that functions to alternately rapidly inflate and deflate the device in a predetermined manner and interval.

The Hygia Health Services Reprocessed NuTech® Combo is substantially equivalent in function, operating parameters, and intended use to the NuTech® Combination Foot and Calf Wrap that is currently commercially available and in distribution. The predicate device, the NuTech® Combination Foot and Calf Wrap, is marked for "single-patient use only." Hygia Health Services does not change the device in any way except to render the device "reusable" by placing it through a scientifically validated thermal kill pasteurization process. The Hygia Health Services HLD protocol does not alter the device's efficacy, safety, composition, or intended use.

5. Description of the Device

The Hygia Health Services Reprocessed NuTech® Combo is a dual compressible limb device for the lower extremities; it is made up of both a foot wrap and a calf wrap. Each devices inflation tube is connected together at a "Y" junction with another single inflation tube exiting the "Y" connector and attaching to the controller. The action of the device occurs only when it is attached to an approved controller. The controller inflates the devices, which provide simultaneous intermittent pneumatic compression of the gastrocnemius muscle and the plantar plexus. Both garments are constructed out of brushed nylon with an elastic lining. The single inflation chambers are constructed from the garment itself. The devices

both have an internal coating of a latex free polymer that creates an airtight seal. The inner lining is elastic, which allows for the inflation. The primary inflation tube is constructed of poly vinyl chloride (PVC), which terminates in a snap-lock connector. The hook fasteners are made of polyethylene. The garments are placed around the gastrocnemius muscle of the calf and the plantar arch of the foot. Both devices are secured with a hook and loop fastener. As the foot garment compresses the plantar plexus, the veins are stretched longitudinally simulating weight-bearing activities. This action causes the veins to empty upward. Then as the calf wrap compresses the gastrocnemius muscle, venous pressure is increased, ejecting the blood upward toward the heart. After a rapid compression, the garment deflates allowing the veins to refill and bring oxygenated blood to the lower limbs. The pressure of compression is determined by the controller and is adjusted by altering the readout on the controller. Both devices inflate simultaneously with a 0.2 second delay between the foot wrap and calf wrap inflation sequence.

6. Intended Use of Device

The Hygia Health Services Reprocessed NuTech® Combo is designed to operate in the identical manner as the predicate device, the NuTech® Combination Foot and Calf Wrap. It is designed to apply compression to a patient's plantar plexus and gastrocnemius muscle for the prevention of deep vein thrombosis (DVT) and as a treatment for edema secondary to venous insufficiency. The compression activities of the device also promote wound healing and reduce compartmental pressures. The device is used in both the home and institutional settings on patient populations for which this device is applicable.

7. Technological Characteristics

The technological characteristics of the Hygia Health Services Reprocessed NuTech® Combo are identical to the original NuTech® Combination Foot and Calf Wrap in overall design, materials, energy source, mode of operation, and performance characteristics. Hygia Health Services employs no new technological characteristics other than the scientifically validated thermal high-level disinfection process.

8. Performance Data

Nonclinical Tests- Comparative bench testing was utilized to assess and prove similarity of function between the Hygia Health Services Reprocessed NuTech® Combo and the predicate device, the NuTech® Combination Foot and Calf Wrap. All tests found that functional and operational performance characteristics including compression, pressure control, and timing sequence were substantially

equivalent. Safety and operational parameters regarding controller connections were also found to be equivalent.

Clinical Tests- Clinical tests were summarized in support of the premarket notification submission.

Test Conclusions- Clinical and nonclinical test results of the Hygia Health Services Reprocessed NuTech® Combo indicated substantial equivalence in all aspects to the predicate device, the NuTech® Combination Foot and Calf Wrap.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2002

Mr. Geoff M. Fatzinger, BS, MS
Director, Compliance/Regulatory Affairs
Hygia Health Services, Inc.
2800 Milan Court, Suite 259
Birmingham, AL 35211

Re: K012956
Trade Name: Hygia Health Services Reprocessed NuTech® Combo
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: February 7, 2002
Received: February 8, 2002

Dear Mr. Fatzinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K012956
Page 1 of 1

Indications For Use

Applicant: Hygia Health Services, Inc.

510(k) Number: K012956

Device Name: Hygia Health Services Reprocessed NuTech® Combo

Indications For Use:

The Hygia Health Services Reprocessed NuTech® Combo is used as a non-invasive therapeutic method by patients in the home or institutional setting in order to:

- Prevent deep vein thrombosis
- Reduce wound healing time
- Treat and assist healing of venous leg ulcers
- Reduce edema caused by venous insufficiency in the lower extremities

PRECAUTIONS AND CONTRAINDICATIONS

Contraindications:

Wraps may not be recommended for patients with the following:

1. Congestive heart failure
2. Known or suspected deep vein thrombosis
3. Severe arteriosclerosis or other ischemic vascular disease
4. Any local leg condition in which the wrap would interfere such as dermatitis, gangrene, recent skin graft, or untreated infected wounds

Precautions:

1. One must ensure that the wrap is applied properly.
2. One must ensure that the wrap is correctly connected to the pump and that the connection is secure.
3. If numbness, tingling, or leg pain is experienced by the patient, the wrap should be removed.

Prescription Use ✓ K012956
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012956